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10/540,123	06/22/2006	Hermann Gohl	07552.0056	1075
22852	7590	02/01/2011		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER STEELE, JENNIFER A	
			ART UNIT	PAPER NUMBER
			1798	
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			02/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,123

Applicant(s)

GOHL ET AL.

Examiner

JENNIFER STEELE

Art Unit

1798

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-19, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 20, 21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/18/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. **Claim 1, 3, 4, 6, 7, 20-21, 24-25 rejected under 35 U.S.C. 103(a) as unpatentable over Nohmi et al (US 4,822,489) in view of Nohmi et al (US 4,399,035).** Claim 1 describes a permselective asymmetric hollow fiber membrane suitable for hemodialysis comprising:

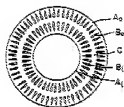
- at least one hydrophobic polymer and
- at least one hydrophilic polymer
- wherein said hollow fiber membrane has a four layer structure comprising
 - a first inner separation layer in the form of a dense rather thin layer
 - a second layer in the form of a sponge structure
 - a third layer in the form of a finger structure
 - and a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 micron, the number of said pores on

the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²

Nohmi '489 is directed to a hollow fiber membrane having a five layer structure with an outer surface, an outer void layer, an intermediate layer, an inner void layer and an inner surface layer. Nohmi '489 teaches the hollow fiber membrane is produced from polysulfone type resin. Nohmi '489 does not teach the polysulfone material is hydrophobic, however Applicant describes polysulfone as hydrophobic. Nohmi '489 teaches the polysulfone fiber can be produced by spinning with a glycol such as ethylene glycol, diethylene glycol, triethylene glycol, polyethylene glycol (col. 9, lines 63-65 and col. 10, lines 44-51) or a polyvinylpyrrolidone (PVP) (col. 10, lines 18-20). Nohmi '489 does not teach a hydrophilic polymer but as Applicant describes the hydrophilic polymer can be a glycol or PVP. Nohmi '489 teaches the same materials as Applicant's specification and therefore the properties are presumed to be inherent or obvious over Nohmi '489.

Nohmi '489 teaches the layers include an outer surface layer A_o, an outer void layer B_o, an intermediate layer C, an inner void layer B_i and an inner surface layer A_i. Where the voids in the void layer have the shape of a cone and are equated with the claimed third layer finger structure. The intermediate layer C has a large number of pores is equated with the second sponge layer. The inner surface layer is equated with the first inner separation layer. The outer surface layer is equated with the outer sponge layer as claimed.

FIG. 1



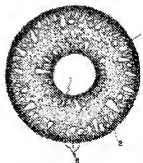
Nohmi '489 differs and does not teach the pore size in the outer surface layer in the claimed range. Nohmi '489 teaches the outer surface has a pore size in the range of 10 to 100 angstroms (col. 3, lines 57-59).

Nohmi '489 differs and does not teach the number of pores on the outer surface.

Nohmi '035 is directed to a hollow filament microfilter (ABST). Nohmi '035 teaches the hollow filament microfilter has a support layer and an internal and external skin layer with an easily controllable and wide average effective pore diameter of 0.05 to 1.0 micron. The hollow filament is characterized by having high selectivity, high permeability, high porosity and excellent mechanical strength and chemical resistance (ABST).

Nohmi '035 is shown below in Fig. 6 where there is an inner layer and an outer layer 1, a support layer 2 which contains macropores and microvoids 3 (col. 13, lines 28-30).

FIG. 6



Nohmi '035 teaches the outer skin layer has pore sizes of 0.05 to 1.0 micron and the number and size of the pores in the skin layers are the determining factors for water permeability and permeation selectivity. The greater the number of pores results in a higher permeability and permeation selectivity. Pore size and pore density are results effective variables which when changed or optimized, effect the permeability and selectivity. Nohmi '035 teaches hollow filaments having 1×10^7 to 1×10^{10} pores/cm² can be obtained (col. 12, lines 57-67). 1×10^7 pores/cm² is equivalent to 100,000 pores/mm² which is in the claimed range.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the pore size and pore density in the outer layer motivated to optimize the permeation selectivity.

As to claim 3, Nohmi '489 and Nohmi '035 differ and do not teach the property of diffusive permeability of urea of $15-17 \times 10^{-4}$ cm/sec. As the combination of Nohmi '489 and Nohmi '035 teach the same materials and structure as claimed it is reasonable to presume that the property is inherent or obvious to the combination. And as the combination of Nohmi '489 and Nohmi '035 teach that one of ordinary skill in the art could optimize the pore size and density in

the skin layer motivated to improve the permeability and selectivity, it would have been obvious to optimize the pore size and density motivated to achieve the desired urea flux.

As to claim 4, Nohmi '489 teaches the thickness of the outer skin layer is almost the same as the inner skin layers and in the range of 0.01 to 10 micron and usually 1 to 4 micron (col. 3, lines 31-36). The inner and outer thickness encompass the claimed range of less than 1 micron for the first separation layer and 1 to 10 micron for the outer layer. Nohmi '489 teaches the second layer or intermediate layer has a thickness of 5 to 70 micron and in the claimed range of 1 to 15 micron. Nohmi '489 teaches the outer void layer with cone shaped voids has a thickness of 10 to 370 micron which is in the claimed range of 20 to 60 micron.

As to claim 6, Nohmi '489 teaches the hollow fiber membrane is produced from a polysulfone polymer.

As to claim 7, Nohmi '489 teaches the hollow fiber membrane can be produced by spinning with a glycol such as ethylene glycol, diethylene glycol, triethylene glycol, polyethylene glycol (col. 9, lines 63-65 and col. 10, lines 44-51) or a polyvinylpyrrolidone (PVP) (col. 10, lines 18-20).

As to claims 20 and 21 which are directed to statements of use, statements of use do not distinguish the claimed invention from prior art. Nohmi '489 is directed to a hollow fiber membrane for ultrafiltration which is in the same field of endeavor as hemofiltration.

As to claims 24 and 25, Nohmi '489 differs and does not teach the pore density on the outer surface.

Nohmi '035 teaches the number of pores on the outer surface can be 100,000 pores per mm^2 which encompasses the claimed range. It would have been obvious to one of ordinary skill

in the art at the time the invention was made to optimize the pore density motivated to achieve the desired permeability and selectivity.

2. Claim 5 rejected under 35 U.S.C. 103(a) as unpatentable over Nohmi et al (US 4,822,489) in view of Nohmi et al (US 4,399,035) and in further view of Buck et al (US 4,935,141).

As to claim 5, Nohmi '489 and Nohmi '035 teach the amount of glycol, or hydrophilic polymer added is in the range of 0.5 to 30% by weight of the spinning solution but differs and does not teach the composition of the membrane. Nohmi '489 teaches a high amount of glycol, over 30%, produces an unstable spinning solution and produces a membrane that can not be put to practical use (col. 11, lines 1-18).

Buck teaches a permeable asymmetric membrane preferably in the shape of hollow fibers (ABST). Buck teaches a three layer membrane with a dense inner layer of thickness of less than 1 micron, a second sponge layer with a thickness of 5 micron and a third open finger like structure having a thickness of 20 to 60 micron. Buck teaches a hydrophobic polymer between about 85-95% and a hydrophilic polymer between about 5-15% (col. 2, lines 26-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the composition of hydrophobic and hydrophilic polymer motivated to produce a hollow fiber membrane which has water permeability yet has high burst strength.

Response to Arguments

3. Applicant's arguments, with respect to Buck, Gorsuch and Wang have been fully considered and are persuasive. The 35 USC 103 rejection of claims 1, 3, 5-7, 20-21 and 24-25 has been withdrawn.
4. Applicant's arguments, with respect to Buck, Gorsuch, Wang and Aptel have been fully considered and are persuasive. The 35 USC 103 rejection of claim 4 has been withdrawn.
5. Applicant's arguments with respect to claims 1, 3-7, 20, 21, 24 and 25 have been considered but are moot in view of the new ground(s) of rejection. As a result this office action is being made NON FINAL.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on (571) 272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1798

1/27/2011